

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA

v.

CASE NO. 1:19cr00016

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC**

**DEFENDANTS' OBJECTIONS TO THE DENIAL OF RULE 17(C) SUBPOENAS
FOR KEY AGENCY MATERIALS RELEVANT TO DOCTORS A-D**

Pursuant to Federal Rule of Criminal Procedure 59(a), Indivior Inc. and Indivior PLC (collectively, "Indivior") respectfully object to a narrow portion of Magistrate Judge Sargent's December 19, 2019 Memorandum Order (ECF No. 247) (hereinafter, "Order") denying in part Indivior's application to issue pre-trial Rule 17(c) subpoenas, with certain requests directed to the Drug Enforcement Administration ("DEA") and Substance Abuse and Mental Health Services Administration ("SAMHSA") for materials critical to Indivior's defense. In the Order, Magistrate Judge Sargent granted in part and denied in part Indivior's Motion to issue Rule 17(c) subpoenas with pre-trial return dates to 11 federal and state agencies. Although Magistrate Judge Sargent rejected a number of the requests for agency materials, Indivior objects only to the denial of its requests for specific materials from the DEA and SAMHSA tied to the four physicians identified in the Superseding Indictment as Doctors A-D.¹ This narrow objection focuses on information that is crucial to Indivior's defense of the government's charges focused

¹ While Indivior's Motion and Magistrate Judge Sargent's Order addressed 11 proposed subpoenas for agency materials to be produced in advance of trial, Indivior reserves its right to request additional subpoenas with pre-trial return dates and to serve subpoenas for documents to be returned on the first day of trial in accordance with Federal Rule of Criminal Procedure 17(c).

on those physicians. Because these requests meet the relevancy, admissibility, and specificity requirements outlined in *United States v. Nixon*, 418 U.S. 683 (1974), Indivior respectfully requests the Court vacate this portion of the Order, grant Indivior's Motion with respect to the requests for the DEA and SAMHSA materials tied to Doctors A-D, and order the Clerk's Office to issue the limited subpoenas attached to this filing as Exhibits A and B.

BACKGROUND

On August 16, 2019, Indivior filed a Motion to Compel (ECF No. 118), requesting that the Court order the government to produce documents from all agencies known to have information material to Indivior's defense, including the DEA and SAMHSA. After Magistrate Judge Sargent denied Indivior's Motion to Compel on October 16, 2019 (ECF No. 220), Indivior sought court approval to issue 11 subpoenas to key federal and state agencies with pre-trial return dates. *See* Def. Motion for Issuance of Pre-Trial Rule 17(c) Subpoenas (ECF No. 229) (hereinafter, "Motion"). As this Court noted in its recent Order denying Indivior's Objections to Magistrate Judge Sargent's Order on the Motion to Compel, Indivior understood the Rule 17(c) process would provide an "alternative mechanism" to obtain the critical materials that are necessary to its defense of this case. *See* Opinion and Order Denying Objections at 12-13 (ECF No. 255) ("[T]he defendants recently requested Rule 17(c) subpoenas for much of the information they initially sought from the government. This demonstrates that the defendants may have an alternative mechanism to obtain the allegedly relevant information.").

In the proposed subpoenas attached to its Motion, Indivior included four key requests directed to the DEA and four similar requests directed to SAMHSA for materials tied to the physicians identified in the Superseding Indictment as Doctors A-D. In the subpoenas and in its Memorandum filed under seal, Indivior explicitly identified these four physicians by name, provided their DEA numbers, and for each physician requested:

- (1) His or her DEA file with the records relating to any audit or investigation of and disciplinary action taken against the physician and any reports submitted by pharmacies to the DEA regarding prescriptions written by the physician; and
- (2) The records reflecting SAMHSA's review and approval of the physician's Drug Addiction Treatment Act ("DATA") of 2000 practitioner waiver and patient limit increase, any consideration of revoking such waiver and patient limit increase, and any audits or investigations completed with regard to the physician.

See Def. Mem. in Support of Mot. for Issuance of Pre-Trial Rule 17(c) Subpoenas at 4-8 (ECF No. 238) (filed under seal); Exhibit A (ECF No. 238-1) (filed under seal); Exhibit B (ECF No. 238-2) (filed under seal).

On December 19, 2019, Magistrate Judge Sargent issued an Order granting some of Indivior's Rule 17(c) subpoena requests and denying a number of others. Among the requests Magistrate Judge Sargent rejected were the physician-specific requests directed to the DEA and SAMHSA. With regard to these requests, Magistrate Judge Sargent stated:

Indivior also seeks to subpoena certain records of the Drug Enforcement Administration, ("DEA"), SAMHSA and six various state agencies regarding seven different physicians, four of whom Indivior states are the four physicians identified in the Superseding Indictment as Doctors A-D. Indivior, however, has not provided the court with any information as to the identities of Doctors A-D or the relevance of the information sought from the other three physicians. The court also finds that the scope of information sought regarding each of these physicians does not meet the specificity requirement of *Nixon*.

Order at 7. Although Indivior also sought key state agency records regarding Doctors A-D and records relating to three other physicians whom Indivior reported to the government (among other agency documents), Indivior is objecting only to the narrow portion of Magistrate Judge Sargent's Order denying its request for the specific records from the DEA and SAMHSA regarding the four physicians explicitly addressed in the Superseding Indictment as Doctors A-D.

LEGAL STANDARD

Under the standard set forth in Rule 59(a), when a party files objections to a magistrate judge's order on a non-dispositive matter, this Court must consider the objections and "modify or

set aside any part of the order that is contrary to law or clearly erroneous.” Fed. R. Crim. P. 59(a). An order is contrary to law “when it fails to apply or misapplies relevant statutes, case law, or rules of procedure.” *United States v. Dunlap*, No. 1:12CR00044-044, 2013 WL 30145, at *1 (W.D. Va. Jan. 2, 2013) (internal quotation marks omitted). And an order is clearly erroneous when “although there is evidence to support it,” the reviewing court, after considering all the evidence, “is left with the definite and firm conviction that a mistake has been committed.” *Minyard Enterprises, Inc. v. Se. Chem. & Solvent Co.*, 184 F.3d 373, 380 (4th Cir. 1999) (internal quotation marks omitted).

As the Fourth Circuit has explained, “Rule 17(c) implements the Sixth Amendment guarantee that an accused have compulsory process to secure evidence in his favor.” *In re Martin Marietta Corp.*, 856 F.2d 619, 621 (4th Cir. 1988). This guarantee, which permits a defendant to serve subpoenas ordering witnesses “to produce any books, papers, documents, data, or other objects [a] subpoena designates,” Fed. R. Crim. P. 17(c), is “considered fundamental to the right to a fair trial,” *United States v. Beckford*, 964 F. Supp. 1010, 1019 (E.D. Va. 1997). In considering whether to permit the return of documents requested in a Rule 17(c) subpoena in advance of trial, courts in this Circuit look to the standard set forth in *Nixon*, which requires:

(1) that the documents are evidentiary and relevant; (2) that they are not otherwise procurable reasonably in advance of trial by exercise of due diligence; (3) that the party cannot properly prepare for trial without such production and inspection in advance of trial and that the failure to obtain such inspection may tend unreasonably to delay the trial; and (4) that the application is made in good faith and is not intended as a general ‘fishing expedition.’

Nixon, 418 U.S. at 699-700. In order to meet these requirements, the requests in a pre-trial Rule 17(c) subpoena “must clear three hurdles: (1) relevancy; (2) admissibility; [and] (3) specificity.” *Id.* at 700; *see also In re Martin*, 856 F.2d at 621 (affirming the district court’s application of the

three *Nixon* factors in ordering the production of materials subpoenaed under Rule 17(c)). Of course, *Nixon* does not require that the materials sought through Rule 17(c) subpoenas actually be used in evidence; “[i]t is only required that a good faith effort be made to obtain evidence” through the Rule 17 process. *In re Martin*, 856 F.2d at 622.

ARGUMENT

The portion of Magistrate Judge Sargent’s Order denying the DEA and SAMHSA requests tied to Doctors A-D is both clearly erroneous and contrary to law. In the first instance, Magistrate Judge Sargent stated that Indivior did not “provide[] the court with any information as to the identities of Doctors A-D.” Order at 7. In fact, Indivior did provide the court with the names and DEA numbers of Doctors A-D in its sealed filings presented with its Motion. *See* Def. Mem. in Support of Mot. for Issuance of Pre-Trial Rule 17(c) Subpoenas at 4-7 (ECF No. 238) (filed under seal) (identifying Doctors A-D in DEA requests 1 through 4 and SAMHSA requests 1 through 4); Exhibit A (ECF No. 238-1) (filed under seal) (identifying Doctors A-D in requests 1 through 4); Exhibit B (ECF No. 238-2) (filed under seal) (identifying Doctors A-D in requests 1 through 4). But more importantly, Indivior provided the court with a fulsome explanation of how the requests tied to these physicians were tailored to meet the requirements set forth in *Nixon* for pre-trial issuance and why the requested materials are not just relevant, but critical to Indivior’s defense of the claims in the Superseding Indictment. *See* Def. Mem. in Support of Mot. for Issuance of Pre-Trial Rule 17(c) Subpoenas at 4-8 (ECF No. 238); Def. Reply in Support of Mot. for Issuance of Pre-Trial Rule 17(c) Subpoenas at 3-7 (ECF No. 244). Instead of analyzing this information and approving the “alternative mechanism” Indivior needed to obtain these critical materials in advance of trial, *see* Opinion and Order Denying Objections at 12-13 (ECF No. 255), Magistrate Judge Sargent’s Order has now denied Indivior access to

these key records tied to claims that are central to the government's case. The net effect of this Court's recent ruling on Indivior's Motion to Compel (ECF No. 255) and, if left undisturbed, Magistrate Judge Sargent's Order on the Rule 17(c) subpoenas, is to prevent Indivior *any* pre-trial access to these DEA and SAMHSA documents, which are both material to Indivior's preparation of its defense and directly relevant to defending the claims alleged in the Superseding Indictment.

As this Court is aware, the Superseding Indictment alleges that Indivior "did aid, abet, counsel, command, induce, and procure physicians . . . who they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner, to switch their prescribing to Suboxone Film." Superseding Indictment ¶ 97 (ECF No. 115); *see also id.* ¶¶ 98-143. In particular, it alleges that Indivior aided and abetted four physicians identified as Doctors A-D who "it knew were issuing careless, clinically unwarranted opioid prescriptions." *Id.* ¶¶ 102-12 (Doctor A); ¶¶ 113-27 (Doctors B & C); ¶¶ 128-43 (Doctor D). Although the Superseding Indictment does not allege that these physicians committed health care or wire fraud or any other kind of criminal offense by prescribing in a "careless and clinically unwarranted manner," the government apparently believes that the physicians' prescribing practices play a central role in the case, *see, e.g.*, Tr. of Oct. 1, 2019 Hearing at 42-43, 45 (ECF No. 205) (insisting that the allegations regarding physicians who prescribe in a "careless and clinically unwarranted manner" are "part of the conspiracy and . . . part of the fraud.").

The evidence requested in Indivior's proposed pre-trial Rule 17(c) subpoenas directed to the DEA and SAMHSA reflects the federal government's understanding of the physicians' prescribing practices, and action or inaction as a result of those practices, which is highly relevant to Indivior's defense. The DEA is the agency that by law registers physicians to prescribe opioids and has the authority to monitor the prescribing activity of registered physicians through, among other things, regular inspections.² The DEA is also authorized to take action against registered physicians who are prescribing illegally.³ SAMHSA is the agency with specific responsibility for overseeing a physician's prescribing of buprenorphine-containing products under DATA 2000.⁴ Accordingly, the requested records will show whether the two federal agencies responsible for monitoring the physicians' prescribing practices viewed any of the physicians' practices to be fraudulent, criminal, or otherwise actionable.

Because it is the DEA and SAMHSA, and not Indivior, that have the ability to assess and remedy physician misconduct, this evidence is critical to Indivior's defense. If the government seeks to prove that Indivior aided and abetted any of the physicians in committing a crime, the requested materials will allow Indivior to show whether the federal government ever actually

² Drug Enforcement Admin., DEA Requirements for DATA Waived Physicians (DWPs), https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm (last visited Jan. 2, 2020) ("Under the authority of the Controlled Substances Act (21 U.S.C. 822(f)), DEA is authorized to conduct periodic on-site inspections of all registrants. DWPs are also subject to on-site inspections to ensure compliance with the DATA and its implementing regulations.").

³ See, e.g., 21 C.F.R. 1301.36; 21 U.S.C. § 824(a). "Under the CSA, DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant has," among other things, "committed an act which would render the DEA registration inconsistent with the public interest." Drug Enforcement Admin., Practitioner's Manual: An Informational Outline of the Controlled Substances Act, 11 (2006). Suspension of any registration can be done immediately with the issuance to show cause in any case in which "there is an imminent danger to the public health or safety." 21 C.F.R. 1301.36(e).

⁴ Substance Abuse & Mental Health Servs. Admin., Practitioner and Program Data, <https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/practitioner-program-data> (last visited Jan. 2, 2020).

believed that the physicians were engaged in unlawful practices.⁵ *See* Superseding Indictment ¶¶ 97-143. Even if, like in the case of Doctor D, an agency action relates to an issue other than the physician’s Suboxone prescribing practices, that evidence will allow Indivior to defend any claim made by the government that Indivior aided and abetted a physician in committing a completely unrelated crime. *See id.* ¶ 143 (“Doctor D indicted on 11/5/2015 for health care fraud related to urine testing”)

Moreover, as explained in Indivior’s Motion, the action or inaction taken by the DEA and SAMHSA with respect to Doctors A-D is relevant to Indivior’s state of mind during its interaction with these physicians over time. Indivior will show that its baseline understanding was that each of the relevant physicians had valid DEA registrations and SAMHSA practitioner waivers, reflecting the federal government’s view that they were qualified to prescribe Indivior’s products. Indivior, as a developer of buprenorphine-containing products that has never been a DEA registrant, has never had an obligation or ability to take any action against physicians if they observed any potentially questionable practices. Instead, Indivior had to trust that the agencies charged with registering these physicians and overseeing their conduct would assess that conduct and, where appropriate, take action to remedy any misconduct. Indivior understands that the records from DEA and SAMHSA will show that neither agency ever took action against these physicians for their buprenorphine prescribing practices, which is directly relevant to whether Indivior had any reason to shift its baseline understanding that each of the physicians was an eligible prescriber of its products at any particular point in time.

⁵ As Indivior has explained in other filings submitted to this Court, it is immaterial to the question of relevance whether the DEA actually ever investigated these physicians. *See, e.g.*, Def. Objections to the Mem. Order Denying Def. Mot. to Compel and Mot. for Bill of Particulars at 5 (ECF No. 226). If it did, and there was no finding or action taken, that information will show that the agency charged with monitoring such activities did not view the physicians’ prescribing practices to be actionable. If it did not, that too shows a lack of concern regarding the physicians’ methods of prescribing.

Given the relevance of the specific materials requested from DEA and SAMHSA regarding Doctors A-D, Indivior anticipates that the materials will be admissible either as non-hearsay evidence under Federal Rule of Evidence 402 or under Federal Rule of Evidence 803(6) or (7) as a record of the agency's regularly conducted activity or to show the absence of any record of such activity. The Fourth Circuit has made clear that Indivior need not meet a higher standard with respect to admissibility and prove that every document that will be produced in response to the subpoenas will be admitted at trial. Instead, "it is only required that a good faith effort be made to obtain evidence" through the Rule 17(c) process. *In re Martin*, 856 F.2d at 622.

Finally, the requests directed to the DEA and SAMHSA for the records tied to Doctors A-D are narrowly tailored in accordance with *Nixon*'s specificity requirement. Specificity does not require that every subpoena request be tailored to a particular document. Instead, courts in this Circuit have held that subpoenas with sharply defined categories of documents are permissible under *Nixon*. See, e.g., *id.* (affirming the district court's issuance of a Rule 17(c) subpoena seeking the results of an internal audit, interview notes, transcripts, and electronic recordings that were "described with sufficient specificity"). Indeed, the *Nixon* Court "recognized that in some instances it may be impossible to 'describe fully' the documents" requested in a Rule 17(c) subpoena, and as a result, "concluded that the specificity requirement could be satisfied if there is a 'sufficient likelihood,' demonstrated through rational inferences, that the documents being sought contain relevant and admissible evidence." *United States v. Libby*, 432 F. Supp. 2d 26, 31 (D.D.C. 2006) (citing *Nixon*, 418 U.S. at 700). The key is that the requests be "made in good faith," without the intent of undertaking "a general 'fishing expedition.'" *Nixon*, 418 U.S. at 700.

Here, Indivior is, in good faith, seeking from both the DEA and SAMHSA a sharply defined category of documents that will allow it to establish the federal government's view of the prescribing practices of Doctors A-D. Unlike cases in which a defendant is seeking complete files of documents with only a hope of finding one or more relevant documents within those files,⁶ all the records Indivior is seeking from the DEA and SAMHSA tied to Doctors A-D will be relevant to showing the government's action or inaction with respect to these physicians over time, and the impact, or lack thereof, on Indivior's understanding of the physicians' qualifications to prescribe buprenorphine-containing products. Rather than seeking broad categories of documents relating to numerous physicians of potential relevance, Indivior is requesting only the relevant documents tied directly to the four physicians who are central to the government's claims.

CONCLUSION

For the foregoing reasons, and for the reasons addressed in Indivior's opening and reply briefs supporting its Motion (ECF Nos. 238, 244), Indivior respectfully requests that the Court vacate the specified portion Magistrate Judge Sargent's Order, grant its request for the DEA and SAMHSA subpoenas tied to Doctors A-D, and order the Clerk to issue those limited subpoenas attached to this filing as Exhibits A and B.

⁶ Cf. *United States v. Ging-Hwang Tsoa*, No. 1:13-cr-137, 2013 WL 5837631, at *1-2 (E.D. Va. Oct. 29, 2013) (considering a request for all documents related to a number of real estate transactions through which the defendant hoped to identify a narrower set of "several documents" she thought would be located within the files); *United States v. Kipp*, No. 3:15-cr-244, 2016 WL 7209581, at *2-3 (W.D.N.C. Dec. 9, 2016) (considering three subpoenas ranging in length from six to nine pages and including requests for all documents and communications on a number of topics, apparently without an accompanying explanation of why such categories were appropriately tailored in the context of the charged conduct in the case).

Dated: January 2, 2020

Respectfully submitted,

INDIVIOR INC. (a/k/a Reckitt Benckiser
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/s/ Thomas J. Bondurant, Jr.

By Counsel

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 2nd day of January, 2020.

/s/ Thomas J. Bondurant, Jr. _____

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